RECEIVED
CENTRAL FAX CENTER

AUG 0 3 2007

REMARKS

This Amendment is responsive to the final Office Action dated May 3, 2007. Applicant has amended claims 2, 6, 11, and 14. Claims 1-12, 14-21 and 32 are pending.

Summary of Examiner Interview

On June 28, 2007, Applicant's representative Jessica H. Kwak conducted a telephone interview with Examiner Christopher A. Flory. Jessica H. Kwak inquired whether Examiner Flory had considered the Supplemental Disclosure Statement filed on October 26, 2006. In addition, Applicant and Examiner Flory discussed the finality of the Office Action mailed on May 3, 2007. No exhibits were introduced, and no agreement was reached with respect to the claims.

Information Disclosure Statement

On October 26, 2006, Applicant filed a Supplemental IDS, before a Notice of Allowance or a Final Rejection, and with the fee set forth in 1.17(p). The Supplemental IDS was filed in order to submit a Declaration under 37 C.F.R. 1.132. At this time, Applicant has not received any indication that the Declaration under 37 C.F.R. 1.132 has been considered. Applicant respectfully requests an indication that the Declaration under 37 C.F.R. 1.132 was considered.

Improper Final Rejection

Applicant requests withdrawal of the finality of the Office Action dated May 3, 2007. According to MPEP 706.07(a), a final rejection on a second action is not proper where a new ground of rejection is introduced that is neither necessitated by Applicant's amendment of the claims nor based on information submitted in an information disclosure statement (IDS) filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p). In the previous Response filed on March 6, 2007, Applicant did not amend any claims. Furthermore, the new ground of rejection presented in the Office Action dated May 3, 2007 is based on information submitted in an IDS filed June 30, 2004, which was prior to a receipt of the first Office Action in the present case.

Due to the failure of the new ground of rejection presented in the Office Action dated May 3, 2007 to meet the aforementioned conditions, the finality of the Office Action dated May 3, 2007 is improper. Withdrawal of the finality of the Office Action dated May 3, 2007 is respectfully requested.

Claim Rejection Under 35 U.S.C. § 103

In the Office Action, claims 1-12, 14, 15, 17-21 and 32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Meadows et al. (U.S. Patent No. 6,516,227, hereinafter referred to as Meadows) in view of Whitehurst et al. (U.S. Patent Application Publication No. 2003/0229383, hereinafter referred to as Whitehurst). In addition, claim 16 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Meadows in view of Whitehurst and further in view of Stanton et al.(U.S. Patent No. 6,249,703, hereinafter referred to as Stanton). In the Response to Arguments, the Office Action also referred to Lee et al. (U.S. Patent No. 6,614,664, hereinafter referred to as Lee) in the rejection of claims 11, 12, and 14, and Causey et al. (U.S. Patent Application Publication No. 2002/0002326, hereinafter referred to as Causey), and Malek (U.S. Patent Application Publication No. 2003/0177031, hereinafter referred to as Malek) in the rejection of claim 15. Applicant respectfully traverses the rejections. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

For example, the applied references fail to disclose or suggest a medical device programmer comprising an infrared interface to receive changes to software executed by a processor within the programmer during an infrared communication session, and a controller to activate the infrared interface to seek an infrared communication session for a finite period of time in response to power-up of the programmer, and deactivate the infrared interface after the finite period of time if the infrared communication session is not established, as recited by Applicant's independent claim 1.

In support of the rejection of claim 1, the Office Action acknowledged that Meadows does not disclose a finite seeking period or deactivation of the infrared interface after a finite period of time if the communication session is not established. However, the Office Action cited Whitehurst as teaching these requirements and reasoned that it would have been obvious to one

of ordinary skill in the art at the time of the invention to modify the system taught by Meadows with the teachings of Whitehurst in order to minimize power consumption. Applicant respectfully disagrees that Whitehurst cures the fundamental deficiencies in Meadows.

As an initial matter, it is unclear why one of ordinary skill in the art contemplating the teachings of Meadows would have even consulted Whitehurst. Whitehurst describes an implanted device with a radiofrequency (RF) telemetry receiver that allows communication with an external remote device. The RF telemetry receiver of the implanted device is periodically activated to conserve power consumption of the implanted device.[1] One of ordinary skill in the art looking to modify an infrared interface of an external medical device programmer as taught by Meadows would not have looked to an implanted medical device with an RF telemetry receiver as taught by Whitehurst.

As one example of the fundamental differences between an external medical device programmer and an implanted medical device as applied to Applicant's claimed invention, the medical device programmer provides a level of manual control that the implanted device of Whitehurst does not allow. For example, the handheld programmer of Meadows may be turned on and off through direct user activation.[2] In contrast, Whitehurst does not describe how the implanted device is powered on. The different degrees of control provided by a programmer compared to an implanted device result in different design criteria. Accordingly, it is unclear why one skilled in the art would have looked to Whitehurst to modify Meadows.

Additionally, even if the teachings of Meadows and Whitehurst were combined, the resulting combination would not meet each and every limitation of Applicant's independent claim 1. Whitehurst describes an RF communication technique for use between an implanted device and an external remote device. Thus, combining the teachings of Meadows and Whitehurst would result in an altered RF interface between the handheld programmer and implantable pulse generator described by Meadows. The infrared interface between the handheld programmer and the clinician programmer taught by Meadows would remain unchanged. Whitehurst fails to disclose or suggest that an RF interface or an infrared interface of the external

[1] Whitehurst at paragraph [0011].
[2] Meadows at column 26, lines 51-52.

remote device is activated for a finite seeking period or deactivated after a finite period of time if the communication session is not established.

Furthermore, the Office Action incorrectly characterized Applicant's claim 1 as requiring a finite communication session. More specifically, the Office Action addressed the limitation that "the infrared communication session is initiated for a finite amount of time.[3]" However, Applicant's claim 1 requires that the infrared interface seeks an infrared communication session for a finite period of time.

The Office Action cited Meadows as teaching multiple, finite communication sessions that occur each time a stimulus parameter is changed or a charging session is initiated. The Office Action also characterized powering down of the handheld programmer after a period of disuse as a terminus of a finite infrared communication session. However, Applicant's claim 1 is not directed toward finite communication sessions but rather a finite seeking period to initiate a communication session. It seems that the Office Action as confused a finite communication period, per Meadows, with a finite seeking period as claimed. Even if the Meadows handheld programmer establishes multiple infrared communication sessions with a clinician programmer, the infrared interface of the handheld programmer may be continuously activated to listen for communication from (e.g., seek a communication session with) the clinician programmer.

The Meadows handheld programmer does not include a controller to deactivate an infrared interface if a communication session is not established after a finite period of time, as required by Applicant's claim 1. On the contrary, Meadows discloses multiple communication sessions having finite periods. The Office Action also stated that "since Meadows discloses multiple subsequent communication sessions, it is indeed inherent that not only is the duration of each session finite, but the duration of time between communications (i.e. the seeking period) is finite."[4] Yet, this statement does not reflect a proper understanding of the actual limitations set forth in Applicant's claims. Applicant disagrees with the Office Action's characterization of the duration of time between each telecommunicative link as a finite period of time for seeking an infrared communication session. The finite period of time set forth in claim 1 does not refer to the period of time between communication sessions, but rather the seeking of a communication

[3] Office Action dated 5/3/07, page 3.
[4] *Id.* at page 9.

session upon activation of the infrared interface. Even if multiple communication sessions are established in the Meadows system, the time between each of the sessions is not the pertinent issue. Again, the finite length limitation in claim 1 pertains to the limited listening period during which the infrared interface seeks a communication session.

With respect to the time periods between communication sessions, which the Office Action has characterized as seeking periods[5], each of these time periods is terminated when a communication session is established, rather than if the communication session is ***not*** established. In fact, because Meadows teaches a system in which the handheld programmer and clinician's programmer, which communicate via infrared interfaces, are always properly synchronized[6], an infrared communication session is likely sought until the communication session is established. This directly contradicts the requirements of Applicant's claim 1.

Applicant's claim 1 also requires that the infrared interface of a medical device programmer is activated to seek a communication session in response to power-up of the medical device programmer. The Office Action stated that it is an inherent property of the Meadows apparatus that the infrared communication session is initiated in response to power-up of the handheld programmer in order for the handheld programmer and the clinician programmer to be appropriately synchronized. Applicant respectfully disagrees with the Office Action's analysis of Meadows.

To support a finding of an inherent disclosure in Meadows, the Office Action must provide a basis in fact or technical reasoning to support that the allegedly inherent characteristic necessarily flows from the teachings of Meadows.[7] It is not an inherent feature of the Meadows apparatus that the infrared interface of the handheld programmer is activated upon power-up of the handheld programmer. For example, the infrared interface of the handheld programmer may be activated upon connection of the clinician programmer to allow proper synchronization with another programmer, which does not necessarily occur at power-up. Meadows teaches that the handheld programmer is selectively connected to a clinician programmer through an infrared serial port using an infrared cable extension.[8] Because the handheld programmer may be

---

[5] *Id.* at page 9.
[6] Meadows at column 17, lines 61-65 and column 36, lines 24-28.
[7] *Ex parte Levy*, 17 USPQ.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)
[8] Meadows at column 31, lines 41-43.

"selectively" connected to the clinician programmer[9], the handheld programmer does not necessarily automatically seek a communication session with the clinician programmer in response to power up. For example, at times, the handheld programmer may communicate with the implantable pulse generator without the presence of the clinician programmer, while at other times, the clinician programmer may be connected to the handheld programmer to allow communication between the clinician programmer and implantable pulse generator.

In view of the Meadows disclosure, it is possible that the infrared interface of the handheld programmer is activated upon connection to the clinician programmer or at in other appropriate time, rather than in response to power-up of the handheld programmer. Accordingly, it does not necessarily flow from the teachings of Meadows that an infrared interface of a programmer that is activated to seek an infrared communication session in response to power-up of the programmer.

The Office Action also stated that interrogation of the implantable pulse generator in response to the activation of the hidden physician screen included on the handheld programmer constitutes seeking an infrared communication session for a finite period of time in response to power-up of the programmer.[10] However, activation of the physician screen does not amount to a power-up of the programmer, as the Office Action contends. Meadows discloses that access to the hidden physician screen is made available through a specified coded button combination. The example Meadows provides is "pressing the IPG button 242 and the up/down buttons 244 and 245 simultaneously, followed by pressing a set sequence of the other buttons, e.g., pressing the SEL button 243 once, followed by the pressing the down button 245 twice."[11] In fact, Meadows specifically teaches that its handheld programmer is powered-on by simply pressing any button, not by activating a physician screen.[12] The physician screen is activated (and hence the subsequent interrogation of the implantable pulse generator occurs) only after a specified combination of buttons are pressed. Furthermore, it is unclear how interrogation of the

[9] *See, e.g.*, claim 1 of Meadows.
[10] Office Action dated 5/3/07, page 10.
[11] Meadows at column 38, lines 22-32.
[12] *Id.* at column 26, lines 51-52.

implantable pulse generator via RF telemetry[13] relates to seeking an infrared communication session.

Whitehurst also fails to teach that the RF telemetry receiver of the implanted device is activated in response to power-up of the implanted device or the external remote device. As described above, Whitehurst does not teach or suggest how its implanted device may be powered on or off. The implanted RF telemetry receiver of the Whitehurst implanted device is activated based on defined time periods that are completely unrelated to a power-up of the programmer. Furthermore, the implanted device taught by Whitehurst does not appear to allow a user to control when the telemetry interface of the implanted medical device is activated.

With respect to claim 2 as amended, the applied references fail to disclose a finite time period of approximately 5 to 10 seconds following power-up to seek a communication session. The Office Action cited Whitehurst as teaching a finite seeking period and deactivation of the infrared interface after a finite period of time if the communication session is not established. However, Whitehurst describes a seeking period of 10 to 200 milliseconds, which is outside of the range of 5 to 10 seconds specified by claim 2.[14] Whitehurst teaches that, "the period of activation [of the RF telemetry system is] . . . sufficiently short so as to allow a reasonably prompt response of the implant . . . "[15] Given the vast difference between a 10 to 200 millisecond time range and a 5 to 10 second time range, Applicant submits Whitehurst does not teach or even suggest a 5 to 10 second listening period for its RF telemetry system, particularly in light of the power limitations[16] of an implanted device. Furthermore, nothing in the cited references provides a teaching or motivation for providing an infrared interface that seeks a communication session for a 5 to 10 second period of time.

In support of the rejection of claim 2, the Office Action cited paragraph 40 of Whitehurst as teaching a seeking time-out period of 10 seconds. As described by Whitehurst at paragraph 40, the timeout period described by this passage of Whitehurst refers to a period of time elapsed after a command is received, rather than a finite period of time following power up of the device.

---

[13] *Id.* at column 23, lines 48-50.
[14] Whitehurst at paragraph [0037].
[15] *Id.* at paragraph [0011].
[16] *Id.* at paragraph [0026].

After the timeout period, the implant switches from a receive mode with a 100 millisecond seeking period to a sleep-listen cycle with a shorter (e.g., 20 millisecond) seeking period.

Additionally, the Office Action reasoned that claims 2 and 20 are obvious because if the Meadows system remains in use for an hour or is always on, the IR interface is active for 5-10 seconds by nature of being on for longer than that. The Office Action also reasoned that if the patient or clinician using the device powers down after 8 seconds, then the infrared interface has been active for 8 seconds, which satisfies the requirements of claim 2.[17] However, Applicant's claim 1 requires a controller that deactivates the infrared interface after the finite period of time if the infrared communication session is not established. The 5-10 seconds recited in claims 2 and 20 refer to a listening period for seeking a communication session, rather than the duration of the communication session itself. Therefore, an IR interface that is on for longer than 5-10 seconds does not meet the requirements of claim 2. Additionally, if a programmer is turned off after 8 seconds, the infrared interface is not necessarily seeking the communication session during that 8 seconds. Even if the infrared interface seeks the communications session during the 8 seconds the Meadows device is used, which Applicant disagrees with, the infrared interface is turned off regardless of whether or not a communication session is established and, therefore, fails to meet the requirements of claim 2.

With respect to claim 3, the applied references do not describe software changes comprising changes to an operating system of the programmer. The Office Action cited columns 16-17, lines 60-13 of Meadows as teaching this limitation. However, this passage refers to operating program data sent to the implantable pulse generator rather than the programmer. Accordingly, Meadows fails to disclose or suggest a programmer including an infrared interface to receive software changes comprising changes to an operating system of the ***programmer***.

The applied references fail to disclose or suggest a software loading port for loading the software upon assembly of the programmer, as recited by claim 6. The applied references also fail to disclose or suggest a plate member placed to cover the loading port, as further required by claim 8. In support of the rejection of claims 6 and 8, the Office Action stated that any electronic device comprising a housing of more than one part and containing software loaded on a memory inherently comprises a software loading port, where the port is consider to be the open portion of

[17] Office Action dated 5/3/07, page 6.

the housing in which the software-loaded circuitry is being inserted or affixed, and the other portion of the housing is considered to be the plate member covering the loading port.[18]

While Applicant respectfully disagrees with the Office Action's interpretation of a "software loading port," Applicant has amended claim 6 to clarify that the programmer comprises a housing defining an aperture to provide access to the software loading port for loading software into memory. Thus, claim 6 as amended clarifies that the software loading port is not the opening in a housing through which software-loaded circuitry is inserted into the housing. Instead, as fully supported by Applicant's specification, such as at paragraphs [0024] and [0110], the software loading port is an interface, accessible from outside the housing, to load software into memory. The housing of the programmer defines an aperture through which the software loading port, i.e., the interface, is accessible upon assembly of the programmer.

As described in the present application, it may be advantageous for a programmer to include a software loading port for loading software upon assembly of the programmer. For example, a plurality of generic programmers having common hardware components may be pre-manufactured and stored, and when a specific type of programmer is ordered, one of the generic programmers may be loaded with the appropriate software through the exposed loading port as one of the final steps in the manufacturing process[19]. The plate member is subsequently placed on the housing to cover the loading port, thereby blocking access to the loading port.

The Office Action reasoned that the "other portion of the housing" is considered to be a plate member. However, the Office Action offered no support for the conclusion that Meadows even includes two housing portions, or that one housing portion necessarily covers an open portion of another housing portion through which "software-loaded circuitry is being inserted or affixed." For at least these reasons, the cited art does not teach or suggest each of the elements of claims 6 and 8 or a motivation for modifying a medical device programmer to arrive at the invention defined by claims 6 and 8.

Applicant's claim 11 describes a first circuit board within the programmer housing, the first circuit board including telemetry circuitry, wherein the telemetry circuit is coupled to an

[18] *Id.* at page 5.
[19] Applicant's disclosure, paragraphs [0024], [0025], and [0076].

antenna and a second circuit board within the programmer housing, the second circuit board including a display and display circuitry.

In support of the rejection of claim 11, the Office Action stated that it would have been an obvious matter of design choice to modify the Meadows system with two circuit boards to simplify manufacturing or reduce the size of the device. The Office Action also reasoned that since many cell phones incorporate a folding, two circuit board design that leaves a footprint half the size of an unfolded, one circuit board design, the two circuit board configuration would have been an obvious design choice to one of ordinary skill in the art. Applicant respectfully disagrees with the Office Action's conclusions of obviousness.

Applicant's claim 11 recites a first circuit board including telemetry circuitry and a second circuit board including a display and display circuitry. The Office Action has failed to address these requirements, and none of the cited references disclose or suggest such a configuration. As disclosed by the Applicant, the separation distance between the circuit boards may serve to reduce the effects of electrical and electromagnetic interference caused by the display on signals transmitted and received by the internal antenna. In addition, the placement of the antenna and display electronics on different circuit boards may reduce electrical and electromagnetic interference.[20]

The Office Action reasoned that Lee provides support for the assertion that "less noise will arise between two components the further apart they are placed . . ."[21] However, Lee neither discloses a device including a first circuit board including telemetry circuitry and a second circuit board including display and display circuitry, as recited by Applicant's claim 11. Even if Lee teaches that "less noise will arise between two components the further apart they are placed . . . ," as the Office Action asserts, one skilled in the art would not have arrived at the invention of Applicant's claim 11 based on the cited references. Nothing in Lee or the cited references teaches or suggests a programmer including first circuit board including telemetry circuitry and a second circuit board including a display and display circuitry. Claims 12 and 14 depend from claim 11 and are also in condition for allowance for at least the reasons discussed with respect to claim 11.

---

[20] *Id.* at paragraph [0120].
[21] Office Action dated 5/3/07, page 10.

Claim 15 recites an internal antenna defining an aperture and a battery bay extending at least partially into the aperture. The Office Action stated that it would have been an obvious matter of design choice to one of ordinary skill in the art to modify the system as taught by Meadows by extending the battery bay into the antenna aperture. The Office Action referred to FIG. 25 of Causey and FIGS. 1A and 1B of Malek as teaching this limitation.[22] Causey's FIG. 25 illustrates computer 1006 in communication with communication station 1008, infusion device 1010, and RF programmer 1012. FIG. 25 of Causey does not illustrate an internal antenna or a battery bay, and certainly does not show a battery bay extending at least partially into an aperture defined by an internal antenna. FIGS. 1A and 1B of Malek also fail to show the claim limitations. Malek illustrates clinician's programmer 102 including remote telemetry unit 240. Remote telemetry unit 240 fits into an aperture on the dorsal side of clinician's programmer 102 and generally includes a telemetry coil, receiver, transmitter, and telemetry processor. FIGS. 1A and 1B of Malek do not illustrate an internal antenna or a battery bay. The cited figures do not illustrate the limitations of claim 15 and, therefore, fail to disclose or suggest each and every element of claim 15.

Additionally, the Office Action stated that Applicant has not disclosed that positioning the batteries inside the aperture defined by the internal antenna provides an advantage, is used for a particular purpose, or solves a stated problem. Even if it were pertinent to the issue of obviousness, which Applicant disputes, it appears that the Office Action may have overlooked paragraph [0100] of Applicant's disclosure, which states positioning of a battery bay to extend at least partially into an aperture defined by the internal antenna can reduce external magnetic interference to the internal antenna by providing an RF load to the internal antenna, enhancing noise immunity.[23]

For at least these reasons, the Office Action has failed to establish a prima facie case for non-patentability of Applicant's claims 1-12, 14, 15-21 and 32 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

---

[22] *Id.* at page 11.
[23] Applicant's disclosure at paragraph [0100].

RECEIVED
CENTRAL FAX CENTER

AUG 0 3 2007

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Office Action's interpretations of the applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: August 3, 2007

By: Jessica H Kwak

SHUMAKER & SIEFFERT, P.A.
1625 Radio Drive, Suite 300
Woodbury, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102

Name: Jessica H. Kwak
Reg. No.: 58,975